

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-26. (Cancelled)

27. (Previously presented) A unit dose of a therapeutic composition comprising about 16 to about 40 μg budesonide, wherein the budesonide

- (a) is in the form of finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μm , and
- (b) is suspended in an aqueous medium.

28. (Currently amended) A therapeutic method of treating ~~a condition an~~ inflammatory condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320 μg per day, delivered as 8 or more unit doses in a metered amount of about 32 μg budesonide per unit dose, wherein each unit dose comprises finely divided budesonide particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μm , the particles being suspended in an aqueous medium.

29. (Previously presented) The therapeutic method of claim 28, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

30. (Previously presented) The therapeutic method of claim 28, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

31. (Previously presented) The therapeutic method of claim 28, wherein the amount of budesonide is about 256 μg per day.

32. (Previously presented) The therapeutic method of claim 28, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

33. (Previously presented) A unit dose of a therapeutic composition consisting of (a) about 32 μg budesonide; and (b) other ingredients comprising
a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;
dextrose;
Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;
disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and
potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,
wherein the budesonide is in the form of finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μm , suspended in an aqueous medium, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

34. (Previously presented) The unit dose of claim 33, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

35. (Previously presented) The unit dose of claim 33, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

36. (Currently amended) A therapeutic method of treating ~~a condition an~~
inflammatory condition of the upper respiratory tract, the method comprising metering into the

nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320 μg per day, delivered as 8 or more unit doses, wherein each unit dose consists of about 32 μg budesonide and other ingredients, the other ingredients comprising

 a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

 dextrose;

 Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

 disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and

 potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

 wherein the budesonide is in the form of finely divided particles, at least 90% having a mass equivalent sphere diameter of less than 20 μm , suspended in an aqueous medium.

37. (Previously presented) The therapeutic method of claim 36, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

38. (Previously presented) The therapeutic method of claim 36, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

39. (Previously presented) The therapeutic method of claim 36, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

40. (Currently amended) A therapeutic method of treating or preventing ~~a condition~~
an inflammatory condition of the upper respiratory tract, the method comprising administering into a nostril of a mammal in need thereof a metered unit dose, the active ingredient of which consists of about 32 μg of budesonide formulated as finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μm , suspended in an aqueous medium.

41. (Previously presented) The therapeutic method of claim 40, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

42. (Previously presented) The therapeutic method of claim 40, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

43. (Previously presented) The therapeutic method of claim 40, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

44. (Currently amended) A therapeutic method of treating ~~a condition an~~ inflammatory condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320 μg per day, delivered as 8 or more unit doses, the active ingredient of each unit dose consisting of about 32 μg budesonide formulated as finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μm , suspended in an aqueous medium.

45. (Previously presented) The therapeutic method of claim 44, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

46. (Previously presented) The therapeutic method of claim 44, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

47. (Previously presented) The therapeutic method of claim 44, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

48. (Previously presented) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32 μ g budesonide, wherein the therapeutic composition additionally comprises

a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

wherein the budesonide is in the form of finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 μ m, suspended in an aqueous medium, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

49. (Previously presented) The unit dose of claim 48, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μ m.

50. (Previously presented) The unit dose of claim 48, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μ m.

51. (Previously presented) The unit dose of claim 48, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

52. (Previously presented) A unit dose of a therapeutic composition comprising about 32 μ g budesonide, wherein the budesonide is in the form of finely divided particles and is suspended in an aqueous medium having a pH between 3.5 and 5.0, said composition being suitable for administration to a mammal in a single dose, wherein the composition includes no more than about 32 μ g budesonide.

53. (Previously presented) The unit dose of claim 52, wherein the pH of the aqueous medium is between 4.2 and 4.6.

54. (Previously presented) The unit dose of claim 52, wherein said composition is suitable for nasal administration to a mammal.

55. (Previously presented) The unit dose of claim 52, wherein the composition contains about 0.6 to 0.7 mg/ml budesonide.

56. (Previously presented) The unit dose of claim 52, further comprising one or more pharmaceutically acceptable additives selected from the group consisting of thickening agents, isotonicity agents, surfactants, chelating agents, and preservatives.

57. (Currently amended) A therapeutic method of treating or preventing ~~a condition~~ an inflammatory condition of the upper respiratory tract, the method comprising administering into a nostril of a mammal in need thereof a metered unit dose of finely divided budesonide particles suspended in an aqueous medium having a pH between 3.5 and 5.0, wherein said metered unit dose consists of about 32 μ g budesonide and one or more ingredients other than budesonide.

58. (Previously presented) The therapeutic method of claim 57, wherein the pH of the aqueous medium is between 4.2 and 4.6.

59. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is seasonal allergic rhinitis.

60. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is perennial allergic rhinitis.

61. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is perennial non-allergic rhinitis.

62. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is chronic sinusitis.

63. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is recurrent sinusitis.

64. (Previously presented) The therapeutic method of claim 57, wherein the condition to be treated is nasal polyps.

65. (Previously presented) The therapeutic method of claim 57, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

66. (Currently amended) A therapeutic method of treating ~~a condition an~~ inflammatory condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320 μ g per day, delivered as 8 or more unit doses in a metered amount of about 32 μ g budesonide per unit dose, wherein each unit dose comprises finely divided budesonide particles suspended in an aqueous medium having a pH between 3.5 and 5.0.

67. (Previously presented) The therapeutic method of claim 66, wherein the pH of the aqueous medium is between 4.2 and 4.6.

68. (Previously presented) A therapeutic method according to claim 66, wherein the amount of budesonide is about 256 μ g per day.

69. (Previously presented) The therapeutic method of claim 66, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

70. (Previously presented) A unit dose of a therapeutic composition consisting of (a) about 32 μ g budesonide; and (b) other ingredients comprising

 a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

 dextrose;

 Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

 disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and

 potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

 wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

71. (Previously presented) The unit dose of claim 70, wherein the pH of the aqueous medium is between 4.2 and 4.6.

72. (Currently amended) A therapeutic method of treating ~~conditions an~~ inflammatory condition of the upper respiratory tract, the method comprising metering into the nose of a mammal a therapeutically effective amount of budesonide that is less than about 320 μ g per day, delivered as 8 or more unit doses, wherein each unit dose consists of about 32 μ g budesonide and other ingredients, the other ingredients comprising

 a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition; disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition, wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0.

73. (Previously presented) The therapeutic method of claim 72, wherein the pH of the aqueous medium is between 4.2 and 4.6.

74. (Previously presented) The therapeutic method of claim 72, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

75. (Previously presented) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32 μ g budesonide formulated as finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said composition being suitable for administration to a mammal in a single dose.

76. (Previously presented) The unit dose of claim 75, wherein the pH of the aqueous medium is between 4.2 and 4.6.

77. (Previously presented) The unit dose of claim 75, wherein the composition contains about 0.6 to 0.7 mg/ml budesonide.

78. (Currently amended) A therapeutic method of treating or preventing ~~conditions~~ an inflammatory condition of the upper respiratory tract, the method comprising administering into a nostril of a mammal a metered unit dose, the active ingredient of which consists of about

32 μ g of budesonide formulated as finely divided particles suspended in an aqueous medium, having a pH between 3.5 and 5.0.

79. (Previously presented) The therapeutic method of claim 78, wherein the pH of the aqueous medium is between 4.2 and 4.6.

80. (Previously presented) The therapeutic method of claim 78, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

81. (Currently amended) A therapeutic method of treating conditions an inflammatory condition of the upper respiratory tract, the method comprising metering into the nose of a mammal a therapeutically effective amount of budesonide that is less than about 320 μ g per day, delivered as 8 or more unit doses, the active ingredient of each unit dose consisting of about 32 μ g budesonide formulated as finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0.

82. (Previously presented) The therapeutic method of claim 81, wherein the pH of the aqueous medium is between 4.2 and 4.6.

83. (Previously presented) The therapeutic method of claim 81, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

84. (Previously presented) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32 μ g budesonide, wherein the therapeutic composition additionally comprises

a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition; dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition; disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition, wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

85. (Previously presented) The unit dose of claim 84, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 μm .

86. (Previously presented) The unit dose of claim 84, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 μm .

87. (Previously presented) The unit dose of claim 84, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

88. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 33.

89. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 34.

90. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 35.

91. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 52.

92. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 53.

93. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 70.

94. (Previously presented) A container containing budesonide and adapted to deliver the unit dose of claim 71.

95. (New) The method of claim 28, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

96. (New) The method of claim 36, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

97. (New) The method of claim 40, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

98. (New) The method of claim 44, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

99. (New) The method of claim 57, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

100. (New) The method of claim 66, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

101. (New) The method of claim 72, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

102. (New) The method of claim 78, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.

103. (New) The method of claim 81, wherein the inflammatory condition of the upper respiratory tract is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, nasal polyps, chronic sinusitis, and recurrent sinusitis.